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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,403	05/24/2007	Laurence Rahme	00786/455003	1332

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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
12/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/586,403	RAHME ET AL.	
	Examiner	Art Unit	
	ROBERT A. ZEMAN	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *2 and 9-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The amendment filed on 9-29-2010 is acknowledged. Claims 1, 7 and 16 have been amended. Claims 1-19 are pending. Claims 2 and 9-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1 and 3-8 are currently under examination.

Claim Rejections Withdrawn

The rejection of claims 1 and 3-8 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is withdrawn in light of the amendment thereto.

Claim Rejection Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1 and 3-8 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues:

1. The amended claims do not require the identification of a pathogen having pathways involving anthranilic acid.

2. If a pathogen does not use anthranilic acid then its production will be immeasurable and the compound cannot further reduce its production.

3. The amended claims no longer require that the candidate compound treats, reduces or prevents a pathogenic infection.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Points 1-3, Applicant is correct that the instant claims no longer require that the candidate compound have efficacy in treating, reducing or preventing a pathogenic infection. However, contrary to Applicant's assertion, the instant claims are not limited to the test compounds. Consequently, even if a given compound had no effect on the production of the molecule set forth in step (b) of claim 1, one would have no idea whether said compound would be ineffective in any other pathogen. Moreover, one would not know if the lack of effect of a given test compound was due to the lack of efficacy of said compound or due to the fact that the test pathogen did not have a pathway involving anthranilic acid. Finally, the instant claims encompass derivatives and precursors of the recited produced molecule. However, the specification is silent with regard to what molecules are encompassed by the terms "precursor" and "derivative". The specification is equally silent with regard to what pathogens produce said precursors and/or derivatives. Without this knowledge the skilled artisan would not know what

molecule to measure in the instant method. Therefor, contrary to Applicant's assertion, proper description is lacking.

As outlined previously, the instant claims are drawn to methods of identifying a compound by measuring the change in anthranilic acid. Said method encompasses all pathogens regardless of the host. Moreover, said method requires identifying microbes possessing a pathway utilizing anthranilic acid wherein modulation of said pathway.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is the measurement of anthranilic acid levels. There is no identification of any structure that must be conserved or the need for any function other than the ability to either directly or indirectly affect anthranilic acid levels in a given pathogen. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical

structure of the encompassed genus of biological molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Given the lack of disclosure of which pathogens contain a pathway which utilizes anthranilic acid, the instant claims do not meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The rejection of claims 1 and 3-8 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues:

1. The amended claims no longer require that the candidate compound treats, reduces or prevents a pathogenic infection.

2. The specification discloses numerous examples of compounds and numerous screening protocols to measure the production of a molecule.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Points 1-2, Applicant is correct that the instant claims no longer require that the candidate compound have efficacy in treating, reducing or preventing a pathogenic infection. However, contrary to Applicant's assertion, the instant claims are not limited to the test compounds. Consequently, even if a given compound had no effect on the production of the molecule set forth in step (b) of claim 1, one would have no idea whether said compound would be ineffective in any other pathogen. Moreover, one would not know if the lack of effect of a given test compound was due to the lack of efficacy of said compound or due to the fact that the test pathogen did not have a pathway involving anthranilic acid. Finally, the instant claims encompass derivatives and precursors of the recited produced molecule. However, the specification is silent with regard to what molecules are encompassed by the terms "precursor" and "derivative". The specification is equally silent with regard to what pathogens produce said precursors and/or derivatives. Without this knowledge the skilled artisan would not know what molecule to measure in the instant method or what screening protocol to use. Therefor, contrary to Applicant's assertion, the instant specification is not enabling.

As outlined previously, the instant claims are drawn to methods of identifying a compound by measuring the change in anthranilic acid. Said method encompasses all pathogens regardless of the host. Moreover, said method requires identifying microbes possessing a pathway utilizing anthranilic acid, its derivatives and or precursors.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claimed invention encompasses an unreasonable number of inoperative compounds, which the skilled artisan would not know how to use. While the specification suggests that one can identify molecules that affect anthrilic acid levels (or those of its precursors and/or derivatives), however, the specification is silent with regard to what molecules are encompassed by the terms "precursor" and "derivative". The specification is equally silent with regard to what pathogens produce said anthrilic acid or its precursors and/or derivatives. Without this knowledge the skilled artisan would not know what molecule to measure in the instant method or what screening protocol to use.

The claims are broad because they do not require the claimed compositions to have any structural limitations nor do they have any functional limitation.

For these reasons, which include the complexity and unpredictability of the nature of the invention and art in terms of the diversity of bioeffective compositions and lack of knowledge

about function(s) of encompassed molecules and their associated pathways, the lack of working examples commensurate with the claimed method, the lack of direction or guidance with regard to the relationship between the anthrilic acid levels and the breadth of the claims with regard to structure and function, it would require undue experimentation to use the invention commensurate in scope with the claims.

New Grounds of Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the use of the phrase "…wherein said compound is identified as reducing production of said molecule relative to production of said molecule by a cell not contacted with said compound." It is unclear how this conclusion can be made without a comparison step. Moreover, the instant claim is not limited to identifying a compound that reduces the production of a given molecule.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m. .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert A. Zeman/
Primary Examiner, Art Unit 1645
December 2, 2010